K014103

BECKMAN COULTER

510(k) Summary
SYNCHRON® Systems Direct LDL Cholesterol Reagent

JAN 2 8 2002

1.0 **Submitted By:**

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2.0 **Date Submitted:**

December 12, 2001

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Direct LDL Cholesterol Reagent

3.2 **Classification Name**

Lipoprotein test system (21 CFR § 862.1475)
Primary calibrator (21 CFR § 862.1150)

4.0 **Predicate Device(s):**

Beckman Coulter	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems Direct LDL Cholesterol (LDLD) Reagent	N-Geneous LDL Cholesterol Reagent	Genzyme Corporation*	K971573

*Genzyme, Corp., Cambridge, MA

5.0 **Description:**

The SYNCHRON System Direct LDL Cholesterol (LDLD) Reagent is designed for optimal performance on the SYNCHRON CX (CX4/4CE/4Δ/4PRO, CX5/5CE/5Δ/5PRO, CX7/7RTS/7Δ/7PRO, CX9ALX/9PRO) and LX (LX20/PRO) Systems. The assay is intended for use in the quantitative determination of low-density lipoprotein cholesterol concentration in human serum or plasma. The reagent kit contains two 100-test cartridges and is packaged with the single-level calibrator.

6.0 **Intended Use:**

LDL Cholesterol (LDLD) Reagent, when used in conjunction with the SYNCHRON® Systems LDLD Calibrator, is intended for the quantitative determination of low-density lipoprotein cholesterol (LDL cholesterol) in human serum or plasma on SYNCHRON Clinical Systems.

7.0 **Comparison to Predicate(s):**

Assay	Aspect/Characteristic	Comments
SIMILARITIES		
SYNCHRON® Systems LDLD Reagent and Calibrator	Intended use	Same as predicate
	Methodology	
	Chemical Reaction	
	Sample Type	
	Sample Size	
	Storage conditions (+2°C to +8°C)	
DIFFERENCES		
	Reportable Range	**SYNCHRON**: 10 to 550 mg/dL **Genzyme***: 6.6 to 992 mg/dL
	Limit of Detection	**SYNCHRON**: 8 mg/dL **Genzyme**: 0.278 mg/dL

*Hitachi 911 analyzer application

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison and imprecision experiments that relate results obtained from the SYNCHRON LDLD Reagent to the Genzyme N-Geneous LDL Cholesterol Reagent on the Hitachi 911 clinical analyzer.

Method Comparison Study Results*

Candidate Method	N	Slope	Intercept	r	Predicate Method**
SYNCHRON LDLD Assay	102	1.044	-2.2	0.991	Genzyme N-Geneous LDL-C Assay

*Serum patient specimens were analyzed in the range of 52 to 192 mg/dL LDL cholesterol. Data shown was collected using SYNCHRON LX Systems. Equivalency between SYNCHRON CX has been established by correlation analysis to SYNCHRON LX Systems.
**Hitachi 911 Analyzer application

Estimated SYNCHRON LX LDLD Assay Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	49.9	1.1	2.2	80
Level 2	211.9	2.9	1.4	80
Level 3	410.4	5.0	1.2	80
Total Imprecision				
Level 1	49.9	1.4	2.9	80
Level 2	211.9	3.8	1.8	80
Level 3	410.4	6.7	1.6	80

The Summary of Safety and Effectiveness information for the SYNCHRON Systems LDLD Reagent is found in TAB 1 of this notice and are being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 8 2002

Ms. Mary Beth Tang
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Brea, CA 92822-8000

Re: k014103
Trade/Device Name: SYNCHRON® Systems Direct LDL Cholesterol Reagent
Regulation Number: 21 CFR 862.1475; 21 CFR 862.1150
Regulation Name: Lipoprotein test system; Calibrator
Regulatory Class: Class I; Class II
Product Code: LBR; JIS
Dated: December 12, 2001
Received: December 13, 2001

Dear Ms. Tang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

510(k) Number (if known): **K014103**

Device Name: **SYNCHRON® Systems Direct LDL Cholesterol Reagent**

Indications for Use:

The SYNCHRON® Systems Direct LDL Cholesterol (LDLD) Reagent, when used in conjunction with SYNCHRON® Systems LDLD Calibrator, is intended for the quantitative determination of low density lipoprotein cholesterol in serum and plasma on Beckman Coulter's SYNCHRON Systems by colorimetry.

LDL cholesterol is directly related to the risk of developing coronary heart disease. A low HDL/LDL cholesterol ratio is directly related to the risk of developing coronary artery disease. Elevated LDL cholesterol is the primary target of cholesterol-lowering therapy.[1]

1. "Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III)", *JAMA*, 285:2486 (2001).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan S. Alpert

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K014103

Prescription Use ✓ (per 21 CFR 801.109) OR Over-the-Counter Use _____

Optional Format 1-2-96